UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

March 17, 2017

MEMORANDUM

Subject: Efficacy Review for CaviCide Bleach;
EPA File Symbol 46781-RL;
DP Barcode: 435859
E-Sub #: 13472

From: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
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To: Demson Fuller PM32/Benjamin Chambliss
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Metrex Research, LLC
1717 West Collins Avenue
Orange, CA 92867

FORMULATION FROM LABEL:

Active Ingredient	% by wt.
Sodium Hypochlorite	0.91%
Other Ingredients	99.09%
Total	100.00%

I BACKGROUND

The proposed product, CaviCide Bleach, is a liquid/spray ready-to-use disinfectant (bactericide, fungicide, tuberculocide, and virucide) for use on hard, non-porous surfaces in commercial and institutional environments. All efficacy studies were conducted at MicroBioTest Labs, located at 105 Carpenter Drive, in Sterling, VA 20164 with the exception of MRID 499890-14 and 499890-35 which were conducted at Accuratus Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained EPA Form 8570-35 (Data Matrix), a proposed product label (identified as Version 08/15/2016), transmittal document, and thirty-eight efficacy studies (MRIDs 499890-05 through 499890-42) with Statements of No Data Confidentiality Claims for all studies embedded in each respective MRID.

II USE DIRECTIONS (proposed)

DISINFECTION directions for use:
[Listing of at least one of the following disinfection instructions, A-E is required:]
***A.* [To disinfect hard, nonporous surfaces:]**
[Spray application:
Spray 6-8 inches from the surface. Let remain visibly wet for 3 minutes. Wipe with a [sponge] [rag] [cloth] [microfiber] [towelette] Gross filth and heavy soil loads must be removed prior to disinfecting.]
***B.* [Direct application:**
Directly [apply] [pour] [this product] with a [cloth] [sponge] [mop] [rag] [towelette] and wet surfaces completely. Let surface remain visibly wet for 3 minutes. [Rinse] [Let air dry.] [Gross filth and heavy soil loads must be removed prior to disinfecting.]
C. [Apply this undiluted product [by] [with a] [sponge] [rag] [cloth] [microfiber] [towelette] [mop] [spraying] [pouring] [or] [immersing] to wet all surfaces thoroughly. When used as directed this [product] [product name] effectively kills the following microorganisms at room temperature [***insert organisms***] [at] [in] 3 minutes.
***D.* [For use as a Disinfectant on non-instrument surfaces:**
Spray CaviCide Bleach directly onto pre-cleaned surface, thoroughly wetting area to be disinfected. Allow surface to remain visibly wet for 3 minutes. Wipe surface using a [towel][wipe] [cloth] allow to air dry]
***E.* [For use as a Disinfectant on Precleaned Non-Critical Medical Devices[1], Instruments and Implements:**
Instruments must by thoroughly cleaned to remove excess organic debris, rinsed and dried. Thoroughly clean and rinse lumens of hollow instruments. Spray CaviCide Bleach directly onto pre-cleaned surface, thoroughly wetting area to be disinfected. Allow surface to remain visibly wet for 3 minutes. Remove and rinse instruments. Wipe dry prior to use.
[1]Non-critical medical devices are items that come in contact only with intact skin.
Note: Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.]

***(¥)*Special Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores.**
Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks and eye covering.
Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with [**Product Name**] [**this product saturated with product name**]. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right

to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

III BRIEF DESCRIPTION OF THE DATA

1. **MRID 499890-05, "AOAC Use Dilution Test – Healthcare," Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538). For product CaviCide Bleach, Lots 16-1081RDO, 16-2081RDO, and 16-1082RDO. Study conducted at MicroBioTest Labs by Kelsey Roach. Study completion date – August 5, 2016. Project Number 198-829.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538). Three lots (Lots 16-1081RDO, 16-2081RDO, and 16-1082RDO) of the product, CaviCide Bleach, were tested using Microbac Protocol No. 198-829. The product was received as a ready to use liquid. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock culture was transferred to an initial 10 mL tube of synthetic broth growth medium, mixed and incubated for 24±2 hours at 35-37°C. A 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 35-37°C. On the day of use, the pellicle was carefully aspirated from the *Pseudomonas aeruginosa* culture by vacuum aspiration. Each test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. For each test culture, the upper portion was removed and pooled in a sterile vessel and mixed. Heat inactivated fetal bovine serum (FBS) was added to each prepared culture to achieve a 5% organic soil load. Carriers were inoculated for 15 minutes (20 carriers per 20 ml inocula) and dried for 40 minutes at 36°C and 30-44% RH. For each organism per test lot, one contaminated carrier was added to each tube; the tubes were swirled gently for 2-3 rotations (avoiding intense swirling or agitation); and the carrier allowed to remain in contact with the test substance for the time specified by the sponsor of the study (three-minute contact time). After the contact time, the carriers were removed, tapped gently against the interior sides of the tube to remove excess disinfectant, transferred to recovery broth with neutralizers and shaken thoroughly. Care was taken to avoid tapping the carrier against the upper third of the tube as well as contact of the carrier to the interior sides of the subculture tube during transfer. All tubes were incubated at 36±1°C for 48±2 hours and the results recorded as visible growth or no visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

2. **MRID 499890-06, "Quantitative Carrier Test to Determine Sporicidal Efficacy Using *Clostridium difficile* Spores," Test Organism: *Clostridium difficile* – spore form (ATCC 43598) for product CaviCide Bleach, Lots 16-1081RDO, 16-2081RDO, and 16-1082RDO. Study conducted at MicroBioTest Labs by Shirshendu Saha. Study completion date – August 8, 2016. Project Number 198-832.**

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598). Lot Nos. 16-1081RDO, 16-2081RDO, and 16-1082RDO of the product, CaviCide Bleach, were tested using MicroBioTest Laboratory Protocol No. 198-832 (copy provided). The product was received as a ready to use liquid.

A stock plate of test organism was used to inoculate 2 pre-reduced 10 mL tubes of Reinforced Clostridial Medium (RCM) using isolated colonies. Each tube was vortex mixed and incubated for 24±2 hours at 35-37°C under anaerobic conditions. Twenty CABA plates were inoculated using the RCM broth culture (100 µL per plate) and incubated for 7-10 days at 36±1°C. The culture was harvested from each plate by adding 5 mL of PBS-T to each plate and gently scraping the surface of each plate with a cell scraper to dislodge the spores. The harvested material was pooled into a sterile 50 mL centrifuge tube and centrifuged at 1650×g for ~38 minutes. The pellet was resuspended in 20-30 mL PBS-T to wash. The wash step was repeated an additional two times and finally resuspended in 4 mL ST80. The spore suspension was heat treated in a water bath for 10±1 minutes at 65±2°C, cooled to room temperature, and evaluated microscopically. Soil was added to the suspension as indicated in the method. HCl Resistance was determined as indicated in the method. For the contamination of carriers, ten (10.0) µL of culture was placed in the center of each disk using a calibrated positive displacement pipettor. After all disks in each petri dish were inoculated, the dishes were covered and the contaminated carriers were placed in a desiccator containing active desiccant. A vacuum was drawn and the carriers were dried for 30±5 minutes under ambient conditions. The Petri dish lids was removed and the carriers were continued to dry under vacuum for 2 hours at room temperature inside the BSC. The test substance (50 µL) was allowed to remain in contact with the disk for 5 minutes at room temperature (21.1-22.1°C). Following the exposure time, 10.0 mL of neutralizer was added to each vial containing the carriers. The vials containing the carriers were vortex-mixed (this represented the 10^0 dilution). The contents were transferred to separate filter membranes with 0.2 µm porosity. The vials were rinsed with 10 mL of sterile PBS and vortex-mixed once. Each rinse solution was transferred to the same filter membrane. The contents were evacuated, after which each filter membrane was removed aseptically from the filter unit and placed on the surface of an agar plate (BHIY-HT Agar) for recovery of *C. difficile* spores. The subcultures were incubated anaerobically for 72±4 hours at 35-37°C prior to spore enumeration. Controls included those for culture purity, carrier sterility, neutralizer sterility, initial suspension population, neutralization confirmation, carrier population, and HCl resistance.

3. MRID 499890-07, "AOAC Use Dilution Test Supplemental," Test Organism: *Burkholderia cepacia* (ATCC 25416). For CaviCide Bleach, Lots 16-1089RDO and 16-2089RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 8, 2016. Project Number 198-852.

This study was conducted against Multi-Drug Resistant *Burkholderia cepacia* (ATCC 25416). Two lots (Lots 16-1089RDO and 16-2089RDO) of the product, CaviCide Bleach, were tested using MICROBIOTEST Laboratory Protocol No. 198-852. The product was received as a ready to use liquid. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. The upper portion was removed and pooled in a sterile vessel and mixed. The final test culture was mixed thoroughly prior to use. A 0.1 mL aliquot of fetal bovine serum was added to 1.9 mL of prepared culture to achieve a 5% organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over 10 individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36°C) and at 56.6% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of

6-8 inches from the carrier surface until thoroughly wet (3 full sprays). The carriers were allowed to remain wet for 1 minute at room temperature 18-25°C (21°C) and at 43% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for less than one day prior to examination. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

4. **MRID 499890-08, "AOAC Use Dilution Test Supplemental," Test Organism: *Escherichia coli* O157:H7 (ATCC 35150). For CaviCide Bleach, Lots 16-1089RDO and 16-2089RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 8, 2016. Project Number 198-853.**

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots (Lots 16-1089RDO and 16-2089RDO) of the product, CaviCide Bleach, were tested using MICROBIOTEST Laboratory Protocol No. 198-853. The product was received as a ready to use liquid. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. The upper portion was removed and pooled in a sterile vessel and mixed. The final test culture was mixed thoroughly prior to use. A 0.1 mL aliquot of fetal bovine serum was added to 1.9 mL of prepared culture to achieve a 5% organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over 10 individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.2-36.4°C) and at 56% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface until thoroughly wet (3 sprays). The carriers were allowed to remain wet for 1 minute at room temperature 18-25°C (20.6°C) and at 35.1% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

5. **MRID 499890-09, "AOAC Use Dilution Test Supplemental," Test Organism: *Klebsiella pneumoniae* (ATCC 4352). For CaviCide Bleach, Lots 16-1089RDO and 16-2089RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 8, 2016. Project Number 198-855.**

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two lots (Lots 16-1089RDO and 16-2089RDO) of the product, CaviCide Bleach, were tested using MICROBIOTEST Laboratory Protocol No. 198-855. The product was received as a ready to use liquid. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-

37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. The upper portion was removed and pooled in a sterile vessel and mixed. The culture was diluted by combining 2.0 mL of test organism suspension with 2.0 mL of sterile growth medium. The final test culture was mixed thoroughly prior to use. A 0.1 mL aliquot of fetal bovine serum was added to 1.9 mL of prepared culture to achieve a 5% organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over 10 individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.2°C) and at 54.6% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface until thoroughly wet (3 full sprays). The carriers were allowed to remain wet for 1 minute at room temperature 18-25°C (20.6°C) and at 34.8% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

6. **MRID 499890-10, "AOAC Use Dilution Test Supplemental," Test Organism: *Legionella pneumophila* (ATCC 33153). For CaviCide Bleach, Lots 16-1089RDO and 16-2089RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – August 8, 2016. Project Number 198-856.**

This study was conducted against *Legionella pneumophila* (ATCC 33153). Two lots (Lots 16-1089RDO and 16-2089RDO) of the product, CaviCide Bleach, were tested using MICROBIOTEST Laboratory Protocol No. 198-856. The product was received as a ready to use liquid. From stock, sufficient Buffered Charcoal Yeast agar (BCYE) plates were inoculated with the test organism and incubated for 3 days at 35-37°C. Following incubation, the test organism was suspended in Butterfield's buffer to approximately match a 2.0 McFarland Turbidity Standard. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of fetal bovine serum was added to 1.90 mL of prepared culture to achieve a 5% organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over 10 individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The carriers were allowed to dry for 30 minutes at 35-37°C (36.2-36.3°C) and at a 54.4% relative humidity. Carriers were used within 2 hours of drying. For each lot of test substance, test carriers were sprayed in a horizontal position, at staggered intervals with the test substance at a distance of 6-8 inches until thoroughly wet (3 full sprays). The carriers were allowed to remain wet for 1 minute at room temperature 18-25°C (21°C) and at 26% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Letheen Broth + 0.14% Lecithin + 1.0% Tween 80 to neutralize. The vessel was shaken thoroughly, vortex mixed, and the subculture broths transferred to a filter membrane pre-wetted with 10 mL of sterile saline and filtered using a vacuum pump. Each filter membrane was washed with ≥50 mL of sterile saline, removed

aseptically from the filter unit and placed on the surface of a BCYE agar plate for recovery of the test organism. All subcultures were incubated for 3 days at 35-37°C in CO_2. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population.

7. **MRID 499890-11, "AOAC Use Dilution Test Supplemental," Test Organism: *Listeria monocytogenes* (ATCC 19117). For CaviCide Bleach, Lots 16-1089RDO and 16-2089RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 8, 2016. Project Number 198-857.**

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots (Lots 16-1089RDO and 16-2089RDO) of the product, CaviCide Bleach, were tested using MICROBIOTEST Laboratory Protocol No. 198-857. The product was received as a ready to use liquid. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). Three additional daily transfers were prepared for testing on 11/3/14. The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. The upper portion was removed and pooled in a sterile vessel and mixed. The culture was diluted by combining 1.0 mL of test organism suspension with 3.0 mL of sterile growth medium (test date 11/3/14). The final test culture was mixed thoroughly prior to use. A 0.1 mL aliquot of fetal bovine serum was added to 1.9 mL of prepared culture to achieve a 5% organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.2-36.3°C) and at 55.7-55.8% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface until thoroughly wet (3 full sprays). The carriers were allowed to remain wet for 1 minute at room temperature 18-25°C (21°C) and at 33-48% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Brain Heart Infusion + 0.28% Lecithin + 2.0% Tween 80 (10/23/14 testing) or Brain Heart Infusion + 0.14% Lecithin + 1.0 % Tween 80 (11/3/14 testing) to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. For testing performed on 10/23/14, subcultures were stored at 2-8°C for less than 1 day prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. One of the 10 test carriers exhibited growth of the target organism; so this study was repeated using 60 test carriers. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

8. **MRID 499890-12, "AOAC Use Dilution Test Supplemental," Test Organism: *Serratia marcescens* (ATCC 14756), for product CaviCide Bleach, 16-1089RDO and 16-2089RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 8, 2016. Project Number 198-858.**

This study was conducted against *Serratia marcescens* (ATCC 14756). Lots 16-1089RDO and 16-2089RDO of the product, CaviCide Bleach, were tested using MICROBIOTEST Laboratory Protocol No. 198-858 (copy provided). The product was

received as a ready to use liquid. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. The upper portion was removed and pooled in a sterile vessel and mixed. The culture was diluted by combining 1.0 mL of test organism suspension with 2.0 mL of sterile growth medium. The final test culture was mixed thoroughly prior to use. A 0.1 mL aliquot of fetal bovine serum was added to 1.9 mL of prepared culture to achieve a 5% organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.1°C) and at 52.8% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface until thoroughly wet (4 full sprays). The carriers were allowed to remain wet for 30 seconds at room temperature (21.6°C) and at 53.7% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Letheen Broth + 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

9. MRID 499890-13, "AOAC Use Dilution Test Supplemental," Test Organism: *Streptococcus pyogenes* (ATCC 12344). For CaviCide Bleach, Lots 16-1089RDO and 16-2089RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 8, 2016. Project Number 198-859.

This study was conducted against *Streptococcus pyogenes* (ATCC 12344). Lots 16-1089RDO and 16-2089RDO of the product, CaviCide Bleach, were tested using MICROBIOTEST Laboratory Protocol No. 198-859. The product was received as a ready to use liquid. A culture of the test organism was prepared by using a stock plate to inoculate multiple agar plates and incubated for 2 days at 35-37°C in CO_2. An organism suspension was prepared in Fluid Thioglycollate Medium to target approximately $1.0x10^8$ CFU/mL. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of broth culture to yield a 5% fetal bovine serum organic soil load. Ten individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface of the slide (approximately 1 square inch) in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 25-30°C (27°C) and at 68% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface until thoroughly wet (3 full sprays). The carriers were allowed to remain wet for 1 minute at room temperature 18-25°C (21°C) and at 22% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Brain Heart Infusion + 0.14% Lecithin + 1.0% Tween 80 to neutralize. The carriers were transferred into individual secondary subcultures containing 20 mL aliquots of secondary subculture medium within ~25-60

minutes of the initial transfer and the vessel was shaken thoroughly. All subcultures were incubated for 2-4 days at 35-37°C in CO_2. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

10. MRID 499890-14, "AOAC Use Dilution Method," Test Organism: *Neisseria gonorrhoeae* (ATCC 43069). For CaviCide Bleach, Lots 16-1130RDO and 16-2130RDO. Study conducted at Accuratus Labs by Melissa Bruner. Study completion date – August 3, 2016. Project Number A21121.

This study was conducted against *Neisseria gonorrhoeae* (ATCC 43069). Lot Nos. 16-1130RDO and 16-2130RDO of the product, CaviCide Bleach, were tested using Accuratus Laboratory Protocol No. MET02052616.UD. The product was received as a ready to use liquid. A culture of the test organism was prepared by using a stock plate to inoculate multiple agar plates and incubated for 2 days at 35-37°C in CO_2. An organism suspension was prepared in Fluid Thioglycollate Medium to target approximately $1.0x10^8$ CFU/mL. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of broth culture to yield a 5% fetal bovine serum organic soil load. Ten individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface of the slide (approximately 1 square inch) in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 25-30°C (27°C) and at 68% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface until thoroughly wet (3 full sprays). The carriers were allowed to remain wet for 1 minute at room temperature 18-25°C (21°C) and at 22% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Brain Heart Infusion + 0.14% Lecithin + 1.0% Tween 80 to neutralize. The carriers were transferred into individual secondary subcultures containing 20 mL aliquots of secondary subculture medium within ~25-60 minutes of the initial transfer and the vessel was shaken thoroughly. All subcultures were incubated for 2-4 days at 35-37°C in CO_2. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

11. MRID 499890-15, "AOAC Use Dilution Test Supplemental," Test Organism: New Delhi metallo-beta-lactamase 1 (NDM-1) positive *Enterobacter cloacae* (CDC 1000654) for product CaviCide Bleach (Lots 16-1089RDO and 16-2089RDO). Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 13, 2016. Project Number 198-845.

This study was conducted against New Delhi metallo-beta-lactamase 1 (NDM-1) positive *Enterobacter cloacae* (CDC 1000654) for product CaviCide Bleach (Lots 16-1089RDO and 16-2089RDO). These were tested using MICROBIOTEST Laboratory Protocol No. 198-845 (copy provided). The product was received as a ready to use liquid. A loopful of stock slant culture was transferred to an initial 10 mL tube of Tryptic Soy Broth growth medium, mixed, and the initial culture was incubated for 24±2 hours at 25-30°C. Following incubation, a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 25-30°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. Then the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted using sterile growth medium by combining 2.00

mL of test organism suspension with 2.00 mL of sterile growth medium. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) individual sterile glass slide carriers (18 mm x 36 mm) per batch, each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approx. 1 square inch) of the slide and covered immediately. This was repeated until all slides were individually inoculated. The culture was vortex mixed periodically during inoculation as necessary. The slides were allowed to dry for 31 minutes at 36.1-36.2°C and at 41% relative humidity, appeared visibly dry, and were used within 2 hours of drying. For each lot of test substance, test carriers (in an undisturbed horizontal position) were sprayed with the test substance at staggered intervals at a distance of 6-8 inches using 3 sprays, and sprayed within ±3 seconds of the exposure time following a calibrated timer. Each treated carrier was then held at room temperature (20.9°C) and 30.9% relative humidity for 1 minute. After exposure, excess liquid was drained off the carrier without touching the carrier to the Petri dish or filter paper. Each carrier was then transferred using sterile forceps following identical staggered intervals to 20 mL aliquots of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80). The vessel was shaken thoroughly. All subcultures were incubated for 48±2 hours at 25-30°C, stored at 2-8°C for 1 day, and then visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population.
Note: Antibiotic sensitivity testing was performed using a representative culture from the day of testing to verify the stated antibiotic resistance pattern: this was performed at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, Minnesota.

12. MRID 499890-16, "AOAC Use Dilution Test Supplemental," Test Organism: Multi-Drug Resistant (MDR) *Acinetobacter baumannii* (ATCC BAA-1605) for product CaviCide Bleach (Lot 16-1089RDO and Lot 16-2089RDO). Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 13, 2016. Project Number 198-846.

This study was conducted against Multi-Drug Resistant (MDR) *Acinetobacter baumannii* (ATCC BAA-1605) for product CaviCide Bleach (Lots 16-1089RDO and 16-2089RDO) using MICROBIOTEST Laboratory Protocol No. 198-846 (copy provided). The product was received as a ready to use liquid. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (Nutrient Broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) individual sterile glass slide carriers (18 mm x 36 mm) per batch, each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approx. 1 square inch) of the slide and covered immediately. This was repeated until all slides were individually inoculated. The culture was vortex mixed periodically during inoculation as necessary. The carriers were allowed to dry for 30 minutes at 35-37°C at 56.2% relative humidity and appeared visibly dry, and were used in the test procedure within 2 hours of drying. For each lot of test substance, test carriers (in an undisturbed horizontal position) were sprayed with the

test substance at staggered intervals at a distance of 6-8 inches using 3 sprays, and sprayed within ±3 seconds of the exposure time following a calibrated timer. Following treatment, each carrier was held at room temperature (21.4°C) and 29.3% relative humidity for 1 minute. After exposure time, excess liquid was drained off the carrier without touching the carrier to the Petri dish or filter paper. Each carrier was then transferred using sterile forceps and following identical staggered intervals to 20 mL aliquots of neutralizing subculture medium (Letheen Broth with 0.14 % Lecithin + 1.0% Tween 80). The vessel was shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C, then stored at 2-8°C for 2 days, and then visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population. Note: Antibiotic sensitivity testing was performed using a representative culture from the day of testing to verify the stated antibiotic resistance pattern: this was performed at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, Minnesota.

13. MRID 499890-17, "AOAC Use Dilution Test Supplemental," Test Organism: Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) for product CaviCide Bleach (Lot 16-1089RDO and Lot 16-2089RDO). Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 13, 2016. Project Number 198-847.

This study was conducted against Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) for product CaviCide Bleach (Lots 16-1089RDO and 16-2089RDO) using MICROBIOTEST Laboratory Protocol No. 198-847 (copy provided). The product was received as a ready to use liquid. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (Nutrient Broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) individual sterile glass slide carriers (18 mm x 36 mm) per batch, each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approx. 1 square inch) of the slide and covered immediately. This was repeated until all slides were individually inoculated. The culture was vortex mixed periodically during inoculation as necessary. The carriers were allowed to dry for 30 minutes at 35-37°C at 41% relative humidity and appeared visibly dry, and were used in the test procedure within 2 hours of drying. For each lot of test substance, test carriers (in an undisturbed horizontal position) were sprayed with the test substance at staggered intervals at a distance of 6-8 inches using 3 sprays, and sprayed within ±3 seconds of the exposure time following a calibrated timer. Following treatment, each carrier was held at room temperature (21.1°C) and 30.5% relative humidity for 1 minute. After exposure time, excess liquid was drained off the carrier without touching the carrier to the Petri dish or filter paper. Each carrier was then transferred using sterile forceps and following identical staggered intervals to 20 mL aliquots of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80). The vessel was shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C, then stored at 2-8°C for 2 days, and then visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population. Note: Antibiotic susceptibility testing was performed by MICROBIOTEST Labs for Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705) to verify the antimicrobial resistance pattern stated. A

modified Hodge test was performed, using a representative culture from the day of testing, confirming both carbapenemase activity and resistance by target organism.

14. MRID 499890-18, "AOAC Use Dilution Test Supplemental," Test Organism: Methicillin Resistant *Staphylococcus aureus* MRSA (ATCC 33592) for product CaviCide Bleach (Lot 16-1089RDO and Lot 16-2089RDO). Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 13, 2016. Project Number 198-848.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* MRSA (ATCC 33592) for product CaviCide Bleach (Lots 16-1089RDO and 16-2089RDO). These were tested using MICROBIOTEST Laboratory Protocol No. 198-848 (copy provided). The product was received as a ready to use liquid. A loopful of stock slant culture was transferred to an initial 10 mL tube of Synthetic Broth growth medium, mixed, and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. Then the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) individual sterile glass slide carriers (18 mm x 36 mm) per batch, each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approx. 1 square inch) of the slide and covered immediately. This was repeated until all slides were individually inoculated. The culture was vortex mixed periodically during inoculation as necessary. The slides were allowed to dry for 30 minutes at 36.1°C and at 41% relative humidity, appeared visibly dry, and were used within 2 hours of drying. For each lot of test substance, test carriers (in an undisturbed horizontal position) were sprayed with the test substance at staggered intervals at a distance of 6-8 inches using 3 sprays, and sprayed within ±3 seconds of the exposure time following a calibrated timer. Each treated carrier was then held at room temperature (20.1°C) and 36.0% relative humidity for 1 minute. After exposure, excess liquid was drained off the carrier without touching the carrier to the Petri dish or filter paper. Each carrier was then transferred using sterile forceps following identical staggered intervals to 20 mL aliquots of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80). The vessel was shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C, stored at 2-8°C for 1 day, and then visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population. Note: Antibiotic resistance testing was performed at MICROBIOTEST Labs (Kirby Bauer susceptibility assay).

15. MRID 499890-19, "AOAC Use Dilution Test Supplemental," Test Organism: Penicillin Resistant *Streptococcus pneumoniae* (ATCC 700677) for product CaviCide Bleach (Lot 16-1089RDO and Lot 16-2089RDO). Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 13, 2016. Project Number 198-849.

This study was conducted against Penicillin Resistant *Streptococcus pneumoniae* (ATCC 700677) for product CaviCide Bleach (Lots 16-1089RDO and 16-2089RDO) using MICROBIOTEST Laboratory Protocol No. 198-849 (copy provided). The product was received as a ready to use liquid. A culture of the test organism was prepared by using a stock plate to inoculate multiple agar plates containing Tryptic Soy Agar with 5% Sheep Blood (BAP) and incubating for 2-3 days at 36°C in 6% CO_2. Following incubation, an

organism suspension was prepared in Fluid Thioglycollate Medium to target 1 x 10^8 CFU/mL. A spec value of 1.302 at 620 nm was prepared. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of the prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) individual sterile glass slide carriers (18 mm x 36 mm) per batch, each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approx. 1 square inch) of the slide and covered immediately. This was repeated until all slides were individually inoculated. The culture was vortex mixed periodically during inoculation as necessary. The carriers were allowed to dry for 30 minutes at 27°C at 67% relative humidity and appeared visibly dry, and were used in the test procedure within 2 hours of drying. For each lot of test substance, test carriers (in an undisturbed horizontal position) were sprayed with the test substance at staggered intervals at a distance of 6-8 inches using 3 sprays, and sprayed within ±3 seconds of the exposure time following a calibrated timer. Following treatment, each carrier was held at room temperature (21°C) and 22% relative humidity for 1 minute. After exposure time, excess liquid was drained off the carrier without touching the carrier to the Petri dish or filter paper. Each carrier was then transferred using sterile forceps and following identical staggered intervals to 20 mL aliquots of primary neutralizing subculture medium (Brain Heart Infusion+ 0.14% Lecithin +1.0% Tween 80). The vessel was shaken thoroughly. The carriers were transferred into individual secondary subcultures containing 20 mL aliquots of secondary subculture medium (same as primary) within approximately 25-60 minutes of the initial transfer and the vessel was shaken thoroughly. All subcultures were incubated for 2-4 days at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population. Note: Antibiotic susceptibility testing was performed by MICROBIOTEST Labs to verify the antimicrobial resistance pattern stated. The Etest® assay was performed utilizing a representative culture from the day of testing.

16. **MRID 499890-20, "AOAC Use Dilution Test Supplemental," Test Organism: Vancomycin Resistant *Staphylococcus aureus* - VRSA (VRS1) for product CaviCide Bleach (Lot 16-1089RDO and Lot 16-2089RDO). Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 13, 2016. Project Number 198-850.**

This study was conducted against Vancomycin Resistant *Staphylococcus aureus* -VRSA (VRS1) for product CaviCide Bleach (Lots 16-1089RDO and 16-2089RDO). These were tested using MICROBIOTEST Laboratory Protocol No. 198-850 (copy provided). The product was received as a ready to use liquid. From stock, multiple agar plates containing Tryptic Soy Agar with 5% Sheep Blood (BAP) were inoculated and incubated for 2 days at 35-37°C. Following incubation, the organism was suspended in sterile Butterfield's Buffer to match a 0.5 McFarland turbidity standard. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) individual sterile glass slide carriers (18 mm x 36 mm) per batch, each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approx. 1 square inch) of the slide and covered immediately. This was repeated until all slides were individually inoculated. The culture was vortex mixed periodically during inoculation as necessary. The slides were allowed to dry for 31 minutes at 36.0-36.1°C at 40% relative humidity, appeared visibly dry, and were used within 2 hours of drying. For each lot of test substance, test carriers (in an undisturbed horizontal position) were sprayed with the test substance at staggered intervals at a distance of 6-8 inches using 3 sprays, and sprayed within ±3 seconds of the exposure time following a calibrated timer. Each treated carrier was then held at room temperature (20.4°C) and 28.0% relative humidity for 1 minute. After

exposure, excess liquid was drained off the carrier without touching the carrier to the Petri dish or filter paper. Each carrier was then transferred using sterile forceps following identical staggered intervals to 20 mL aliquots of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80). The vessel was shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C, stored at 2-8°C for 1 day, and then visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population. Note: Antibiotic susceptibility testing was performed by MICROBIOTEST Labs to verify the antimicrobial resistance pattern stated. The Etest® assay was performed utilizing a representative culture from the day of testing.

17. **MRID 499890-21, "AOAC Use Dilution Test Supplemental," Test Organism: Vancomycin Resistant *Enterococcus faecalis* – VRE (ATCC 51575) for product CaviCide Bleach (Lot 16-1089RDO and Lot 16-2089RDO). Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 13, 2016. Project Number 198-851.**

This study was conducted against Vancomycin Resistant *Enterococcus faecalis* – VRE (ATCC 51575) for product CaviCide Bleach (Lots 16-1089RDO and 16-2089RDO). These were tested using MICROBIOTEST Laboratory Protocol No. 198-851 (copy provided). The product was received as a ready to use liquid. A loopful of stock slant culture was transferred to an initial 10 mL tube of Fluid Thioglycollate growth medium, mixed, and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. Then the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. Sixty (60) individual sterile glass slide carriers (18 mm x 36 mm) per batch, each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approx. 1 square inch) of the slide and covered immediately. This was repeated until all slides were individually inoculated. The culture was vortex mixed periodically during inoculation as necessary. The slides were allowed to dry for 30 minutes at 27°C and at 65% relative humidity, appeared visibly dry, and were used within 2 hours of drying. For each lot of test substance, test carriers (in an undisturbed horizontal position) were sprayed with the test substance at staggered intervals at a distance of 6-8 inches using 3 sprays, and sprayed within ±3 seconds of the exposure time following a calibrated timer. Each treated carrier was then held at room temperature (21°C) and 31% relative humidity for 1 minute. After exposure, excess liquid was drained off the carrier without touching the carrier to the Petri dish or filter paper. Each carrier was then transferred using sterile forceps following identical staggered intervals to 20 mL aliquots of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80). The vessel was shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C, and then visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population. Note: Antibiotic susceptibility testing was performed by MICROBIOTEST Labs to verify the antimicrobial resistance pattern stated. The Kirby Bauer susceptibility assay was performed utilizing a representative culture from the day of testing.

18. **MRID 499890-22, "AOAC Use Dilution Test Supplemental," Test Organism: Extended-Spectrum beta-lactamase (ESBL) positive *Escherichia coli* (ATCC BAA-196) for product CaviCide Bleach (Lot 16-1089RDO and Lot 16-**

2089RDO). Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 8, 2016. Project Number 198-854.

This study was conducted against Extended-Spectrum beta-lactamase (ESBL) positive *Escherichia coli* (ATCC BAA-196) for product CaviCide Bleach (Lots 16-1089RDO and 16-2089RDO) using MICROBIOTEST Laboratory Protocol No. 198-854 (copy provided). The product was received as a ready to use liquid. A loopful of stock slant culture was transferred to an initial 10 mL tube of growth medium (Synthetic Broth). The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.00 mL of sterile growth medium. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. Ten (10) individual sterile glass slide carriers (18 mm x 36 mm) per batch, each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The culture was vortex mixed periodically during inoculation as necessary. The carriers were allowed to dry for 30 minutes at 35-37°C at 52.5% relative humidity and appeared visibly dry, and were used in the test procedure within 2 hours of drying. For each lot of test substance, test carriers (in an undisturbed horizontal position) were sprayed with the test substance at staggered intervals at a distance of 6-8 inches using 3 sprays. The carrier was sprayed with the test substance within ±3 seconds of the exposure time following a calibrated timer. Following the spray treatment, each treated carrier was held at room temperature (21.0°C) and 29.9% relative humidity for 1 minute. At the end of the exposure time, the excess liquid was drained off the carrier without touching the carrier to the Petri dish or filter paper. Each treated carrier was then transferred using sterile forceps and following identical staggered intervals to 20 mL aliquots of neutralizing subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80). The vessel was shaken thoroughly. All subcultures were incubated for 48±2 hours at 35-37°C, then stored at 2-8°C for 2 days, then visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population. Note: Antibiotic susceptibility testing was performed by MICROBIOTEST Labs to verify the antimicrobial resistance pattern stated. The Etest® assay was performed utilizing a representative culture from the day of testing.

19. **MRID 499890-23, "AOAC Tuberculocidal Activity of Disinfectants," Test Organism: *Mycobacterium bovis* – BCG, for product CaviCide Bleach, Lot 16-1081RDO and Lot 16-1082RDO. Study conducted at MICROBIOTEST Labs by Shirshendu Saha. Study completion date – August 5, 2016. Project Number 198-830.**

This study was conducted against *Mycobacterium bovis* – BCG, for product CaviCide Bleach, Lots 16-1081RDO and 16-1082RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-830 (copy provided). The product was received as a ready to use liquid. A stock culture of the test organism, on 7H11 agar medium, was transferred into 20 mL tubes of Modified Proskauer-Beck Broth using ≤10 µL loopful (two 1 µL loopfuls) of culture and incubated for 21 days at 35-37°C in a slanted position. The test culture was then transferred to a sterile tissue grinder containing 1.00

mL of 0.85% saline + 0.1% tween 80 and was macerated to break up large clumps of the test organism. A 9.0 mL aliquot of Modified Proskauer-Beck Broth was added and, after settling for 10-15 minutes, the upper portion was removed and the suspension was transferred to a sterile vessel. This culture was standardized to 19.62% Transmittance (%T) at 650 nm. A 0.10 mL aliquot of FBS was added to 1.90 mL of broth culture to yield a 5% fetal bovine serum organic soil load. Sterile 18 mm x 36 mm glass slide carriers, each in a sterile plastic Petri dish matted with two pieces of filter paper, were each inoculated with 0.01 ml (10.0 µL) of culture using a calibrated pipettor and the inoculum was spread over the surface of the slide (approximately 1 square inch). Each dish was covered and the slides were allowed to dry for 30 minutes at 35-37°C (36.2-36.3°C) and at 55.5% relative humidity. The carriers were used in the test procedure within 2 hours of drying. For each lot of test substance, 10 test carriers were sprayed with the test substance at a distance of 6-8 inches from the carrier surface using 3 full sprays and were allowed to expose for 1 minute at room temperature (22.6°C) and at 37.8% relative humidity. Following the exposure period, the excess liquid was drained off and the individual carriers were transferred at identical staggered intervals to 20 mL of Horse serum to neutralize. The carrier in the neutralizer was shaken and was transferred to a vessel containing 20 mL of Modified Proskauer-Beck Broth. Within 30 minutes of neutralization, a 2.0 mL aliquot of the neutralized solution was transferred to individual vessels containing 20 mL of Middlebrook 7H9 Broth and 20 mL of Kirchner's Medium. All subculture broths were incubated at 35-37°C under aerobic conditions and were visually examined for growth following 61-day incubations. All test subcultures demonstrated a lack of growth, therefore the subcultures were incubated an additional 30 days and re-examined. Controls included those for purity, sterility, visibility, initial suspension population, neutralization confirmation and carrier population.

20. MRID 499890-24, "Virucidal Hard-Surface Efficacy Test," Test Organism: Adenovirus Type 2, Strain Adenoid 75, ATCC VR-5, for product CaviCide Bleach, Lot 16-1081RDO and Lot 16-1082RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 26, 2016. Project Number 198-835.

This study was conducted against Adenovirus type 5, ATCC VR-5, Strain Adenoid 75 for product CaviCide Bleach, Lots 16-1081RDO and 16-1082RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-835 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed, combined and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator Cell cultures of A-549 (human lung carcinoma) cells (ATCC CCL-185) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 40% for 20 minutes. For each lot of test substance, dried virus films were exposed for 30 seconds at room temperature (20.0°C) to 4 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The A-549 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified

atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for eleven days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

21. MRID 499890-25, "Virucidal Hard-Surface Efficacy Test," Test Organism: Hepatitis A virus, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-871.

This study was conducted against Hepatitis A virus Strain HM-175, from AppTec Laboratory Services, Camden, NJ, for product CaviCide Bleach, Lots 16-1089RDO and 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-871 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed, combined and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator Cell cultures of FRhK-4 cells (fetal Rhesus monkey kidney, ATCC CRL-1688) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B and 2.0 mM L-glutamine. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, dried virus films were exposed for 30 seconds at room temperature (21.0°C) to 4 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The A-549 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for 14 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

22. MRID 499890-26, "Virucidal Hard-Surface Efficacy Test," Test Organism: Feline Calicivirus as a Surrogate Virus for Norovirus, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – August 5, 2016. Project Number 198-872.

This study was conducted against Feline Calicivirus (F-9 strain, ATCC VR-782) as a Surrogate Virus for Norovirus for product CaviCide Bleach, Lots 16-1089RDO and 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-872 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator Cell Cultures consisted of cultures of Crandel Reese feline kidney (CRFK) cells (ATCC CCL-94). Cultures were maintained and used in suspension in tissue culture labware at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL

penicillin and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, two dried virus film were individually exposed for 30 seconds at room temperature (21.0°C) to 4 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The MT-2 cells in multiwell culture dishes were inoculated in quadruplicate with 200 µL of the dilutions prepared from test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% C02 in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

23. MRID 499890-27, "Virucidal Hard Surface Efficacy Test," Test Organism: Poliovirus type 1, for product CaviCide Bleach, Lot 16-1082RDO and Lot 16-2081RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 20, 2016. Project Number 198-836.

This study was conducted against Poliovirus type 1, ATCC VR-1562, Strain Chat for product CaviCide Bleach, Lot 16-1082RDO and Lot 16-2081RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-836 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed, combined and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator Cell cultures of Vero cells (ATCC CCL-81) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 15.5°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, dried virus films were exposed for 30 seconds at room temperature (20.0°C) to 4 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The A-549 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

24. MRID 499890-28, "Virucidal Hard-Surface Efficacy Test," Test Organism: Rhinovirus type 37 Strain 151-1 (ATCC VR-1147), for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-837.

This study was conducted against Rhinovirus type 37 (ATCC VR-1147, Strain 151-1) for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-837 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator Cell cultures of MRC-5 (human embryonic lung) cells (ATCC CCL-171) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 15.5°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, one dried virus film was individually exposed for 30 seconds at room temperature (21.0°C) to 4 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The WI-38 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

25. MRID 499890-29, "Virucidal Hard-Surface Efficacy Test," Test Organism: Enterovirus EV-D68, ATCC VR-561, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-874.

This study was conducted against Enterovirus EV-D68, ATCC VR-561, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using Microbac Laboratory Protocol No. 198-874 (copy provided). The product was received as a ready to use liquid. On the day of use, aliquots of stock virus were thawed, combined and maintained at a refrigerated temperature until used in the assay. The stock virus contained 5% fetal bovine serum as the organic soil load. Host Cell cultures of Vero cells (ATCC CCL-81) were seeded into multiwell cell culture plates and maintained at 36±2°C in a humidified atmosphere at 5±1% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 0.5µg/mL Trypsin. Dried virus films were prepared by spreading 0.4 mL of test virus inoculum uniformly over a 4-inch square area of the bottoms of separate sterile glass petri dishes, one for each lot of the test substance and one for the plate recovery control. These were dried at 19-21°C in a relative humidity of 9.0% to 9.1% for 30 minutes. For each lot of test substance, dried virus film on the surface of each glass petri dish carrier was exposed for 1 minute at room temperature (19.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. At the end of the exposure time the virus-test substance mixtures were neutralized with MEM + 0.5% Lecithin and the mixture was scraped from the surface of the carrier with a cell scraper (10^{-1} dilution) and serial ten-fold dilutions of the inoculum/test substance/neutralizer mixture were inoculated into multi well host Vero cell plates (at least 4 wells per dilution). These were incubated at 36±2°C with 5±1% CO_2 for 6-9 days and were assayed for infectivity and/or cytotoxicity. Controls included those for cytotoxicity, plate recovery, cell viability, virus stock titer, infectivity, and neutralization control.

26. MRID 499890-30, "Virucidal Hard-Surface Efficacy Test," Test Organism: Rotavirus, Strain WA, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-875.

This study was conducted against Rotavirus, Strain WA, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-875 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator cell cultures of MA-104 (Rhesus monkey kidney) cells (ATCC CRL-2378.1) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 0.5 µg/mL trypsin and 2.0 mM L-glutamine. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, one dried virus film was individually exposed for 1 minute at room temperature (21.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The MA-104 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups. The inoculum was allowed to adsorb for sixty minutes at 36-38°C in a humidified atmosphere of 5-7% CO_2, then 1.0 mL of test medium was added to each well and the cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO2 in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

27. MRID 499890-31, "Virucidal Hard-Surface Efficacy Test," Test Organism: Herpes simplex virus type 1, Strain F(1), ATCC VR-733, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 26, 2016. Project Number 198-862.

This study was conducted against Herpes simplex virus type 1, ATCC VR-733, Strain F(1), for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-862 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus contained 5% fetal bovine serum as the organic soil load. Indicator cell cultures of Vero cells (ATCC CCL-81) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, one dried virus film was individually exposed for 1 minute at room

temperature (20.5°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Vero cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

28. MRID 499890-32, "Virucidal Hard-Surface Efficacy Test," Test Organism: Herpes simplex virus type 2, Strain G, ATCC VR-734, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 26, 2016. Project Number 198-863.

This study was conducted against Herpes simplex virus type 2, ATCC VR-734, Strain G, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-863 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus contained 5% fetal bovine serum as the organic soil load. Indicator cell cultures of Vero cells (ATCC CCL-81) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, one dried virus film was individually exposed for 1 minute at room temperature (21.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Vero cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

29. MRID 499890-33, "Virucidal Hard-Surface Efficacy Test," Test Organism: Human Coronavirus, Strain 229E, ATCC VR-740, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-864.

This study was conducted against Human Coronavirus, ATCC VR-740, Strain 229E, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-864 (copy provided). The

product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator cell cultures of WI-38 (human lung) cells (ATCC CCL-75) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, one dried virus film was individually exposed for 1 minute at room temperature (20.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The WI-38 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for 10 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

30. **MRID 499890-34, "Virucidal Hard-Surface Efficacy Test," Test Organism: Influenza A (H7N9) virus (Strain wildtype A/Anhui/1/2013, CDC # 2013759189), for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-865.**

This study was conducted against Influenza A (H7N9) virus (CDC # 2013759189, Strain wildtype A/Anhui/1/2013) for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-865 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator Cell cultures of MDCK (canine kidney) cells (ATCC CCL-34) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 2 µg/mL TPCK-trypsin, 25 mM HEPES, 0.2% BSA fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 21.0°C in a relative humidity of 45.89% for 20 minutes. For each lot of test substance, one dried virus film was individually exposed for 1 minute at room temperature (21.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The MDCK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for 6 days for the absence or

presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

31. MRID 499890-35, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Influenza B virus, Strain B/Hong Kong/5/72, ATCC VR-823, for product CaviCide Bleach, Lot 16-1130RDO and Lot 16-2130RDO. Study conducted at Accuratus Labs by Melissa Bruner. Study completion date – July 12, 2016. Project Number A21148.

This study was conducted against Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72, for product CaviCide Bleach, Lot 16-1130RDO and Lot 16-2130RDO. These were tested using Accuratus Laboratory Protocol No. A21148 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator Cell cultures of MDCK (canine kidney) cells (ATCC CCL-34) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 2 µg/mL TPCK-trypsin, 25 mM HEPES, 0.2% BSA fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 40% for 20 minutes. For each lot of test substance, one dried virus film was individually exposed for 1 minute at room temperature (20.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately 22passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The MDCK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

32. MRID 499890-36, "Virucidal Hard-Surface Efficacy Test," Utilizing Duck Hepatitis B Virus as a Surrogate for Human Hepatitis B Virus, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-866.

This study was conducted against the Grimaud strain of Duck Hepatitis B Virus (DHBV) as a Surrogate for Human Hepatitis B Virus, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-866 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. On the day of use, three aliquots of stock virus were thawed, combined and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum in addition to whole duck serum (100% duck serum) as the organic soil load. Indicator Cell cultures of viral free duckling hepatocytes, obtained from VRI Labs, were seeded into sterile twelve well disposable tissue culture labware and were maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Leibovitz

L-15 medium supplemented with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 6 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 44.5% for 30 minutes. For each lot of test substance, two dried virus films were exposed for 1 minute at room temperature (20.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Primary duck hepatocyte cells in multiwell culture dishes were inoculated in quadruplicate with 250 µL of the dilutions prepared from test and control groups and were incubated for 9 days at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. On the final day of incubation, the cultures were scored microscopically for cytotoxicity and the cells were fixed with ethanol. An indirect immunofluorescence assay was performed using a monoclonal antibody specific for the envelope protein of the DHBV. Controls included those for input virus control, dried virus control, cytotoxicity, neutralization and cell viability.

33. MRID 499890-37, "Virucidal Hard-Surface Efficacy Test," Utilizing Bovine Viral Diarrhea Virus as a Surrogate for Human Hepatitis C Virus, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-867.

This study was conducted against the NADL strain of Bovine Viral Diarrhea Virus (BVDV) as a Surrogate for Human Hepatitis C Virus, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-867 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. On the day of use, two aliquots of stock virus were thawed, combined and maintained at a refrigerated temperature until used in the assay. The stock virus contained 5% horse serum as the organic soil load. Indicator Cell cultures of bovine turbinate (BT) cells (ATCC CRL-1390), were maintained, and used at the appropriate density in tissue culture labware at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 5% (v/v) non-heat inactivated horse serum, supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin and 2.0 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 6 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, two dried virus films were exposed for 1 minute at room temperature (21.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The BT cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 in sterile disposable cell culture labware. The cultures were microscopically scored periodically for seven days for the absence or presence of CPE, cytotoxicity, and for viability. On the final day of incubation, a direct immunofluorescence assay (DFA) was performed using a polyclonal fluorescein conjugated antibody specific for BVDV. The DFA

was performed on the 10^{-1} and 10^{-2} dilution of the test and the 10^{-4} and 10^{-5} dilutions of the dried virus control. Controls included those for input virus control, dried virus control, cytotoxicity, neutralization and cell viability.

34. MRID 499890-38, "Virucidal Hard-Surface Efficacy Test," Test Organism: Human Immunodeficiency Virus type 1, Strain HTLV-III_B, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-868.

This study was conducted against Human Immunodeficiency Virus type 1 (Strain HTLV-III_B), for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-868 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator Cell Cultures consisted of cultures of MT-2 cells (human T-cell leukemia cells), obtained through the AIDS Research and Reference Reagent Program. Cultures were maintained and used in suspension in tissue culture labware at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was RPMI-1640 supplemented with 15% (v/v) heat-inactivated FBS supplemented with 2.0 mM L-glutamine and 50 µg/mL gentamicin. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 21.0°C in a relative humidity of 43.7% for 20 minutes. For each lot of test substance, one dried virus film was individually exposed for 1 minute at room temperature (20.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The MT-2 cells in multiwell culture dishes were inoculated in quadruplicate with 200 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% $C0_2$ in sterile disposable cell culture labware. The cultures were scored periodically for 14 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

35. MRID 499890-39, "Virucidal Hard-Surface Efficacy Test," Test Organism: Respiratory Syncytial Virus (RSV), Strain Long, ATCC VR-26, for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Zheng Chen. Study completion date – July 27, 2016. Project Number 198-869.

This study was conducted against Respiratory Syncytial Virus (ATCC VR-26, Strain Long), for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-869 (copy provided). The product was received as a ready to use liquid. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum as the organic soil load. Indicator Cell cultures of Hep-2 (human larynx carcinoma) cells (ATCC CCL-23) were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, and 1.0

mM L-glutamine. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. For each lot of test substance, one dried virus film was individually exposed for 1 minute at room temperature (21.0°C) to 3 sprays at a distance of 6-8 inches and held covered for the exposure time. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Hep-2 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% C02 in sterile disposable cell culture labware. The cultures were scored periodically for 9 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

36. **MRID 499890-40, "AOAC Use Dilution Test Supplemental," Test Organism: *Candida albicans* (ATCC 10231), for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – July 8, 2016. Project Number 198-860.**

This study was conducted against *Candida albicans* (ATCC 10231) for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-860 (copy provided). The product was received ready to use liquid. From a stock culture slant of the test organism, a loopful of culture was transferred to a sufficient number of 10 mL tubes of Sabouraud Dextrose Broth and incubated for 48-54 hours at 25-30°C. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. Ten individual sterile glass slide carriers per lot (18 mm x 36 mm), each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 25-30°C (27.0°C) and at 62% relative humidity. Carriers were used within 2 hours of drying. For each lot of test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface using 3 full sprays. The carriers were allowed to remain wet for 1 minute at 18-25°C (20.9°C) and at 29.5% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of subculture medium, Sabouraud Dextrose Broth + 0.14% Lecithin + 1.0% Tween 80 to neutralize. All neutralized subcultures were incubated for 2 days at 25-30°C. Subcultures were stored at 2-8°C for 1 day prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population

37. **MRID 499890-41, "Fungicidal AOAC Use Dilution Test Supplemental," Test Organism: *Aspergillus brasiliensis* (ATCC 16404), for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – August 8, 2016. Project Number 198-861.**

This study was conducted against *Aspergillus brasiliensis* (ATCC 16404) for product CaviCide Bleach, Lot 16-1089RDO and Lot 16-2089RDO. These were tested using MICROBIOTEST Laboratory Protocol No. 198-861 (copy provided). The product was received as a ready to use liquid. From a stock culture slant of the test organism, a loopful of culture was transferred to a sufficient number of 10 mL tubes of Sabouraud Agar modified and incubated for 10 days at 25-30°C. Following incubation, saline/Triton Solution and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidial concentration was estimated by counting in a hemacytometer. The conidial count was determined to be $1.1x10^8$ conidia/mL. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. Ten individual sterile glass slide carriers per lot (18 mm x 36 mm), each in a Petri dish matted with two pieces of filter paper, were inoculated with 10.0 µL of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 31 minutes at 35-37°C (36.1-36.2°C) and at 56.8% relative humidity. Carriers were used within 2 hours of drying. For each lot of test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface using 4 full sprays. The carriers were allowed to remain wet for 1 minute at room temperature (24.3°C) and at 48.2% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of subculture medium, Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80, and 0.05% sodium thiosulfate to neutralize. All neutralized subcultures were incubated for 10 days at 25-30°C. Agar plate subcultures were incubated at 25-30°C for 44-76 hours. Agar plate subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation and carrier population

38. MRID 499890-42, "AOAC Use Dilution Test," Test Organism: *Trichophyton mentagrophytes*, (ATCC 9533), for product CaviCide Bleach, Lot 16-1082RDO and Lot 16-2081RDO. Study conducted at MICROBIOTEST Labs by Kelsey Roach. Study completion date – August 8, 2016. Project Number 198-833.

This study was conducted against *Trichophyton mentagrophytes*, (ATCC 9533), for product CaviCide Bleach, Lot 16-1082RDO and Lot 16-2081RDO. These were tested using Microbac Laboratory protocol 198-833 (copy provided). The product was received as a ready to use liquid. From a stock culture of the test organism, agar plates were inoculated and incubated at 25-30°C for ≥10, but ≤15 days. The mycelial mat was macerated and then filtered through sterile gauze to remove hyphal fragments. The density of the conidial suspensions was determined by standard plate count techniques. Heat-activated Fetal Bovine Serum (FBS) was added to the inoculum to yield a 5% fetal bovine serum organic soil load. Ten individual sterile glass slide carriers, each in a Petri dish matted with filter paper, were inoculated with 0.01 mL (10.0 µL) of test organism using a calibrated pipettor. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 37°C and at 19-26% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface using 4 pump sprays. The carriers were allowed to remain wet for 1 minute at room temperature (20°C) and at 17-19% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the

individual carriers were transferred using sterile forceps at staggered intervals to 20 mL of Neopeptone Glucose Broth containing 0.2% Sodium Thiosulfate to neutralize. All neutralized subcultures were incubated for 10 days at 25-30°. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralization confirmation, carrier counts, inoculum counts, viability, fungistasis control and confirmation of challenge fungus.

IV RESULTS

MRID Number	Organism	Lot #	No. Exhibiting Growth / Total No. Carriers Tested	Carrier Population (Log_{10}CFU/ Carrier)
3 Minute Exposure Time				
499890-05	*Staphylococcus aureus* (ATCC 6538)	16-1081RDO 16-2081RDO 16-1082RDO	1/60 1/60 1/60	6.71
	Pseudomonas aeruginosa (ATCC 15442)	16-1081RDO 16-2081RDO 16-1082RDO	4/60 1/60 3/60	6.55
	Salmonella enterica (ATCC 10708)	16-1081RDO 16-2081RDO 16-1082RDO	1/60 1/60 1/60	6.62

MRID Number	Organism	Lot No.	Mean Log_{10} CFU/Carrier (LD) Recovered	Mean Log_{10} CFU/Carrier (LD) Initially Present	Log Reduction
3 Minute Exposure Time					
499890-06	*Clostridium difficile*- spore form (ATCC 43598)	16-1081RDO	0.13	6.36	6.23
		16-2081RDO	0.00	6.34	6.34
		16-1082RDO	-0.02	6.36	6.36

MRID Organism	Subculture Medium	Lot #	No. Exhibiting Growth / Total No. Carriers Tested	Carrier Population (Log_{10}CFU/ Carrier)
3 Minute Exposure Time				
499890-23 *Mycobacterium bovis* (BCG)	Modified Proskauer-Beck Broth	16-2081RDO 16-1082RDO	0/10 0/10	5.12
	Middlebrook 7H9 Broth	16-2081RDO 16-1082RDO	0/10 0/10	
	Kirchner's Medium	16-2081RDO 16-1082RDO	0/10 0/10	

MRID Number	Organism	Lot #	No. Exhibiting Growth / Total No. Carriers Tested	Carrier Population Avg. CFU/ Carrier
3-Minute Exposure Time				
499890-40	*Candida albicans* (ATCC 10231)	16-1089RDO	0/10	4.4×10^5
		16-2089RDO	0/10	
499890-42	*Trichophyton mentagrophytes* (ATCC 9533)	16-2081RDO	0/10	3.3×10^4
		16-1082RDO	0/10	
499890-41	*Aspergillus brasiliensis* (ATCC 16404)	16-1089RDO	0/10	1.0×10^6
		16-2089RDO	0/10	

MRID Number	Organism	Lot #	No. Exhibiting Growth / Total No. Carriers Tested	Carrier Population (Log_{10}CFU/ Carrier)
3-minute Exposure Time				
499890-07	*Burkholderia cepacia* (ATCC 25416)	16-1089RDO 16-2089RDO	0/10 0/10	6.61
499890-08	*Escherichia coli* O157:H7 (ATCC 35150)	16-1089RDO 16-2089RDO	0/10 0/10	6.71
499890-09	*Klebsiella pneumoniae* (ATCC 4352)	16-1089RDO 16-2089RDO	0/10 0/10	6.87
499890-10	*Legionella pneumophila* (ATCC 33153)	16-1089RDO 16-2089RDO	0/10 0/10	5.69
499890-11	*Listeria monocytogenes* (ATCC 19117)	16-1089RDO 16-2089RDO	0/10 0/10	6.34
499890-14	*Neisseria gonorrhoeae* (ATCC 43069)	16-1130RDO 16-2130RDO	0/10 0/10	5.22
499890-12	*Serratia marcescens* (ATCC 14756)	16-1089RDO 16-2089RDO	0/10 0/10	6.72

MRID Number	Organism	Lot #.	No. Exhibiting Growth / Total No. Carriers Tested	Carrier Population (Log_{10}CFU/ Carrier)
3-minute Exposure Time				
499890-13	*Streptococcus pyogenes* (ATCC 12344)	16-1089RDO 16-2089RDO	0/10 0/10	4.79
499890-16	Multi-Drug Resistant (MDR) *Acinetobacter baumannii* (ATCC BAA-1605)	16-1089RDO 16-2089RDO	0/10 0/10	5.96
499890-17	Carbapenem Resistant *Klebsiella pneumoniae* (ATCC BAA-1705)	16-1089RDO 16-2089RDO	0/10 0/10	5.88
499890-22	Extended-Spectrum beta-lactamase (ESBL) positive *Escherichia coli* (ATCC BAA-196)	16-1089RDO 16-2089RDO	0/10 0/10	6.41
499890-18	Methicillin Resistant *Staphylococcus aureus* MRSA (ATCC 33592)	16-1089RDO 16-2089RDO	0/10 0/10	5.80
499890-15	New Delhi metallo-beta-lactamase 1 (NDM-1) positive *Enterobacter cloacae* (CDC 1000654)	16-1089RDO 16-2089RDO	0/10 0/10	6.68
499890-19	Penicillin Resistant *Streptococcus pneumoniae* (ATCC 700677)	16-1089RDO 16-2089RDO	0/10 0/10	5.98
499890-21	Vancomycin Resistant *Enterococcus faecalis* – VRE (ATCC 51575)	16-1089RDO 16-2089RDO	0/10 0/10	5.81
499890-20	Vancomycin Resistant *Staphylococcus aureus* - VRSA (VRS1)	16-1089RDO 16-2089RDO	0/10 0/10	5.67

MRID Number	Organism	Results			Dried Virus Count
3-Minute Exposure Time					
			16-1089RDO	16-2089RDO	
499890-25	Hepatitis A Virus, Strain HM175/18f	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤2.10
		Log Reduction	≥3.25	≥3.25	
499890-26	Feline Calicivirus, Strain F9 ATCC VR-782	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤3.40
		Log Reduction	≥3.52	≥3.52	
499890-30	Rotavirus, Strain WA ATCC VR-2018	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤2.10
		Log Reduction	≥3.75	≥3.75	
499890-28	Rhinovirus Type 37, Strain 151-1, ATCC VR-1147	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤3.40
		Log Reduction	≥3.38	≥3.38	
499890-31	Herpes simplex virus type 1, Strain HF ATCC VR-260	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤2.40
		Log Reduction	≥4.63	≥4.63	
499890-32	Herpes simplex virus type 2, Strain G, ATCC VR-734	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤2.40
		Log Reduction	≥3.75	≥3.75	
499890-33	Human Coronavirus, Strain 229E, ATCC VR-740	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤2.10
		Log Reduction	≥4.00	≥4.00	
499890-29	Enterovirus EV-D68 ATCC VR-561	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤2.10
		Log Reduction	≥3.50	≥3.50	
499890-34	Influenza A virus (H3N2), Strain Hong Kong/8/68	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤2.10
		Log Reduction	≥4.00	≥4.00	
499890-39	Respiratory Syncytial Virus Strain Long, ATCC VR-26	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤3.40
		Log Reduction	≥3.25	≥3.25	
499890-36	Duck Hepatitis B Virus as a Surrogate for Human Hepatitis B Virus, Strain Grimaud	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤1.10
		Log Reduction	≥4.00	≥4.00	
499890-37	Bovine Viral Diarrhea Virus as a Surrogate for Human Hepatitis C Virus, Strain NADL	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤2.40
		Log Reduction	≥3.82	≥3.82	
499890-38	HIV Virus type 1, Strain $HTLV\text{-}III_B$	10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤3.40
		Log Reduction	≥3.38	≥3.38	

MRID Number	Organism	Results			Dried Virus Count
3-Minute Exposure Time					
499890-27	Polio Virus Type 1, Strain Chat, ATCC VR-1562		16-1082RDO	16-2081RDO	
		10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	Log_{10} $TCID_{50}$/ 400 µL ≤2.40
		Log Reduction	≥3.50	≥3.50	

MRID Number	Organism	Results			Dried Virus Count
3-Minute Exposure Time					
499890-35	Influenza B virus ATCC VR-823		16-1130RDO	16-2130RDO	
		10^{-1} to 10^{-6} Dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$ $TCID_{50}$/100 µL
		$TCID_{50}$/100 µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	

MRID Number	Organism	Results			Dried Virus Count
3-Minute Exposure Time					
499890-24	Adenovirus type 2, Strain Adenoid 6, ATCC VR-846		**16-1082RDO**	**16-2081RDO**	Log_{10} ($TCID_{50}$/ 400 µL) Per carrier ≤2.40
		10^{-2} to 10^{-7} Dilutions	Complete inactivation	Complete inactivation	
		Log_{10} Reduction	≥3.50	≥3.50	

V CONCLUSIONS

1.) The submitted efficacy data **support** the ready–to-use product as a disinfectant against the following bacteria on hard, non-porous non-food contact surfaces with a 5% organic soil load for a 3-minute contact time at room temperature:

Salmonella enterica (ATCC 10708)	499890-05
Pseudomonas aeruginosa (ATCC 15442)	499890-05
Staphylococcus aureus (ATCC 6538)	499890-05
Burkholderia cepacia (ATCC 25416)	499890-07
Escherichia coli O157:H7 (ATCC 35150)	499890-08
Klebsiella pneumoniae (ATCC 4352)	499890-09
Legionella pneumophila (ATCC 33153)	499890-10
Listeria monocytogenes (ATCC 19117)	499890-11
Neisseria gonorrhoeae (ATCC 43069)	499890-14
Serratia marcescens (ATCC 14756)	499890-12
Streptococcus pyogenes (ATCC 12344)	499890-13
Multi-Drug Resistant (MDR)	
Acinetobacter baumannii (ATCC BAA-1605)	499890-16
Carbapenem Resistant	
Klebsiella pneumoniae (ATCC BAA-1705)	499890-17
Extended-Spectrum beta-lactamase (ESBL)	
positive *Escherichia coli* (ATCC BAA-196)	499890-22
Methicillin Resistant	
Staphylococcus aureus MRSA (ATCC 33592)	499890-18
New Delhi metallo-beta-lactamase 1 (NDM-1) positive	
Enterobacter cloacae (CDC 1000654)	499890-15
Penicillin Resistant	
Streptococcus pneumoniae (ATCC 700677)	499890-19
Vancomycin Resistant	
Enterococcus faecalis – VRE (ATCC 51575)	499890-21
Vancomycin Resistant	
Staphylococcus aureus -VRSA (VRS1)	499890-20

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2.) The submitted efficacy data **support** the ready–to-use product) as a disinfectant against the following fungi on hard, non-porous non-food contact surfaces with a 5% organic soil load for a 3-minute contact time at room temperature:

Trichophyton mentagrophytes, (ATCC 9533)	499890-42
Candida albicans (ATCC 10231)	499890-40
Aspergillus brasiliensis (ATCC 16404)	499890-41

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3.) The submitted efficacy data **support** the ready–to-use product as a disinfectant against the following viruses on hard, non-porous non- food contact surfaces with a 5% organic soil load for a 3-minute contact time at room temperature (19-21°C):

Hepatitis A Virus, Strain HM175/18f	499890-25
Feline Calicivirus, Strain F9 ATCC VR-782	499890-26
Rotavirus, Strain WA ATCC VR-2018	499890-30
Rhinovirus Type 37, Strain 151-1 ATCC VR-1147	499890-28
Herpes simplex virus type 1, Strain HF, ATCC VR-260	499890-31
Herpes simplex virus type 2, ATCC VR-734, Strain G	499890-32
Human Coronavirus, Strain 229E, ATCC VR-740	499890-33
Enterovirus EV-D68, ATCC VR-561	499890-29
Influenza A virus (H3N2), Strain Hong Kong	499890-34
Respiratory Syncytial Virus (ATCC VR-26, Strain Long)	499890-39
Duck Hepatitis B Virus (DHBV) as a Surrogate for Human Hepatitis B Virus, Grimaud strain	499890-36
Bovine Viral Diarrhea Virus, Strain NADL	499890-37
Human Immunodeficiency Virus type 1 (Strain HTLV-III_B)	499890-38
Polio Virus Type 1, Strain Chat, ATCC VR-1562	499890-27
Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72	499890-35
Adenovirus type 2, Strain Adenoid 6, ATCC VR-846	499890-24

Recoverable virus titers of at least 10^4 were achieved. Complete inactivation (no growth) was indicated in all dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

4.) The submitted efficacy data **support** the ready–to-use product as a disinfectant against the following mycobacterium on hard, non-porous surfaces with a 5% organic soil load for a 3-minute contact time at room temperature:

Mycobacterium bovis – BCG	499890-23

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

5.) The submitted efficacy data **support** the ready–to-use product as a disinfectant against *Clostridium difficile* spores on pre-cleaned, hard, non-porous surfaces for a 3-minute contact time at room temperature:

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

VI RECOMMENDATIONS

1. The label claims that the ready-to-use product is a disinfectant against the following bacteria on hard, non-porous non- food contact surfaces for a 3-minute contact time in the presence of 5% serum load:

Salmonella enterica (ATCC 10708)
Pseudomonas aeruginosa (ATCC 15442)
Staphylococcus aureus (ATCC 6538)

Burkholderia cepacia (ATCC 25416)
Escherichia coli O157:H7 (ATCC 35150)
Klebsiella pneumoniae (ATCC 4352)
Legionella pneumophila (ATCC 33153)
Listeria monocytogenes (ATCC 19117)
Neisseria gonorrhoeae (ATCC 43069)
Serratia marcescens (ATCC 14756)
Streptococcus pyogenes (ATCC 12344)
Multi-Drug Resistant (MDR)
    Acinetobacter baumannii (ATCC BAA-1605)
Carbapenem Resistant
    Klebsiella pneumoniae (ATCC BAA-1705)
Extended-Spectrum beta-lactamase (ESBL)
    positive *Escherichia coli* (ATCC BAA-196)
Methicillin Resistant
    Staphylococcus aureus MRSA (ATCC 33592)
New Delhi metallo-beta-lactamase 1 (NDM-1) positive
    Enterobacter cloacae (CDC 1000654)
Penicillin Resistant
    Streptococcus pneumoniae (ATCC 700677)
Vancomycin Resistant
    Enterococcus faecalis – VRE (ATCC 51575)
Vancomycin Resistant
    Staphylococcus aureus -VRSA (VRS1)

These claims are acceptable as they are supported by the submitted data.

2. The label claims the ready–to-use product is a disinfectant against the following fungi on hard, non-porous non-food contact surfaces for a contact time of 3-minute in the presence of 5% serum load:

Trichophyton mentagrophytes, (ATCC 9533)
Candida albicans (ATCC 10231)
Aspergillus brasiliensis (ATCC 16404)

These claims are acceptable as they are supported by the submitted data.

3. The label claims that the ready-to-use product is a disinfectant against the following viruses on hard, non-porous non- food contact surfaces for a 3-minute contact time in the presence of 5% serum load:

Hepatitis A Virus, Strain HM175/18f
Feline Calicivirus, Strain F9 ATCC VR-782
Rotavirus, Strain WA ATCC VR-2018
Rhinovirus Type 37, Strain 151-1 ATCC VR-1147
Herpes simplex virus type 1, Strain HF, ATCC VR-260
Herpes simplex virus type 2, ATCC VR-734, Strain G
Human Coronavirus, Strain 229E, ATCC VR-740
Enterovirus EV-D68, ATCC VR-561
Influenza A virus (H3N2), Strain Hong Kong
Respiratory Syncytial Virus (ATCC VR-26, Strain Long)
Duck Hepatitis B Virus (DHBV) as a Surrogate for
Human Hepatitis B Virus, Grimaud strain
Bovine Viral Diarrhea Virus, Strain NADL
Human Immunodeficiency Virus type 1 (Strain HTLV-III_B)
Polio Virus Type 1, Strain Chat, ATCC VR-1562
Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72
Adenovirus type 2, Strain Adenoid 6, ATCC VR-846

These claims are acceptable as they are supported by the submitted data.

4. The label claims the ready–to-use product is a disinfectant against the following *Mycobacterium* on hard, non-porous non-food contact surfaces for a 3-minute contact time in the presence of 5% serum load:

Mycobacterium bovis – BCG

This claim is acceptable as it is supported by the submitted data.

5. The label claims the ready–to-use product is a disinfectant against *Clostridium difficile* spores on hard, non-porous non-food contact surfaces for a 3-minute contact time.

This claim is acceptable as it is supported by the submitted data.

VII LABEL RECOMMENDATIONS

Label Recommendations for CaviCide Bleach Reg. No. 46781-RL (For proposed label dated 08/15/2016):

1. On page 4 under the directions for use sections A and B, remove brackets from the following instruction: "Gross filth and heavy soil loads must be removed prior to disinfecting" as this language is not optional. Additionally, this text should be included at the beginning of all other directions for use sections.

2. On page 4, revise the directions for use section E statement "For Use as a Disinfectant on Precleaned Non-Critical Medical Devices, Instruments and Implements" to "For Use as a Disinfectant on Hard, Non-Porous surfaces of Precleaned Non-Critical Medical Devices, Instruments and Implements".

3. The terms "decontaminant" and "decontaminate" should be removed from all locations on the label other than when used under the Special Instructions for HIV-1, HBV, and HCV (page 6). The Agency has a different testing requirement for decontaminants specified in the OCSPP 810.2100 guidelines.

4. On page 8 of the proposed label, registrant should revise the organism list labeled "Multidrug-Resistant Bacteria." The only multidrug resistant organisms that would qualify for this "multi-drug resistant" list are ESBL *Escherichia coli* and Multi-drug resistant *Acinetobacter baumannii.* The rest of the organisms should be placed under a heading labeled "Drug-Resistant Bacteria" or be placed under the "Bacteria" heading. Another option is to list all drug-resistant organisms under a heading labeled "Drug Resistant Bacteria."

5. On page 9, correct the name of the organism "*Trichophyton mentagrophytes*" to read "*Trichophyton interdigitale* (ATCC 9533) (formerly mentagrophytes)."

6. On pages 10 and 12 within the 4th and 3rd bullets respectively remove all organisms other than *C. difficile* or change the 6-log (99.9999%) reduction claims to 3-log.

7. On page 10 of the proposed label:
    a. Revise the claim, "A 1:10 sodium hypochlorite solution similar to that recommended by the CDC for effective disinfecting..." to "Representative of a 1:10 sodium hypochlorite solution similar to that recommended by the CDC for effective disinfecting..."
    b. Remove the stand-alone claim "sporicidal". Although the product is a disinfectant against *C. difficile* spores, this does not qualify it to be a general sporicide which has different testing requirements from those required for the *C. difficile* claim.

8. On page 11 of the proposed label:
    a. Remove "the risk of" from the claim "Can help reduce the risk of cross contamination on treated surfaces."
    b. Remove the claim "[Concentration of hypochlorite in CaviCide Bleach meets the disinfection requirements of a 1:10 dilution of bleach]." This implies that additional disinfection requirements (other than those specified under FIFRA) were obtained for this product.
    c. Change the concentration of 1000 PPM of available chlorine to 5000 PPM available chlorine in the two claims, "[Contains a concentration of 1000 PPM or higher available chlorine..." as this is the minimum concentration referenced in the CDC citations.

9. Throughout the label claims of cleaning and disinfecting in one step, such as "[Cleans] [disinfects] [cleaner and disinfectant] [in one] [all in one[easy] step]" should include language similar to "...when disinfection directions are followed".

10. Throughout the label, registrant should qualify all "viruses", "virus" and "virucidal" claims with an asterisk referencing the labeled viruses.

11. On page 14 of the proposed label:
    a. Remove the claim "Eliminates airborne particles associated with sprays". The meaning of this claim is not clear and is misleading.
    b. Revise the claim, "...[[Fight[s] -and/or- stop[s] -and/or- help[s] prevent[s] -and/or reduce[s] the spread of [99.99% of] [illness-causing] bacteria-and/or- viruses* -and/or- germs on hard, nonporous surfaces [in your ▲] [this flu season]" to indicate 99.9%.
    c. The optional phrase "the hazard of" should be removed from the claim "For use in critical care areas where control of [the hazards of] cross contamination is of prime importance". This claim is misleading because it implies a reduction in the occurrence of disease transmission.

12. On page 15 of the proposed label:
    a. Revise the claim "Helps prevent cross contamination on treated surfaces" to "Helps reduce cross contamination on treated hard, non-porous surfaces".
    b. Remove the claim "Intermediate Level Disinfectant". EPA has no criteria for this type of level of disinfectant.
    c. Qualify the claims "Kills multi drug resistant organisms" and "Kills multi drug resistant bacteria" to reference the two multidrug resistant organisms tested.

13. On page 17 and throughout the proposed label:
    a. Qualify "Pseudomonocidal" and "Staphylocidal" claims with an asterisk to reference the specific strains tested. The stand-alone claims are considered to be too broad.
    b. Remove all claims of reducing the "exposure" to certain organisms claimed.
    c. Remove all claims of reducing the "risk" of cross contamination. These claims are misleading as they imply a reduction of the risk of disease transmission.
    d. Remove the claim, "Shelf-stable formula", which is considered misleading because it implies stability beyond the standard requirement.

14. On page 18 and throughout the proposed label:
    a. Remove all claims to fight or reduce "outbreaks", "transmission" and to "control of the hazards" of cross contamination. These claims are misleading as they imply a reduction in the occurrence of disease transmission.

15. On page 19:
    a. Remove the claim of reducing "exposure" to *C. difficile*.
    b. Remove the claim to control the "hazards" of cross contamination as this implies a reduction in the occurrence of disease transmission.

16. On page 24 of Table 7, registrant should remove claims for dental retainers, dental impressions and impression materials, dental intra-oral cameras, and any other objects that come in contact with the oral mucosa of the mouth.

17. Under the table for surfaces, registrant should add the word "plastic" in front of the claim, Mattress Covers and add "exterior surfaces of" in front of the claims toilet, ultrasound Transducers, and urinals.

18. On page 3 of the label, the following text should be added to the draft label immediately prior to the current emerging pathogens language:

"This product meets the criteria for use against the following categories of emerging viral pathogens when used in accordance with the use directions for Poliovirus type 1 and Rhinovirus type 37:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses"